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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/527,414	11/09/2006	Todd Campbell	PA1211	4776

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MEDTRONIC VASCULAR, INC.  
IP LEGAL DEPARTMENT  
3576 UNOCAL PLACE  
SANTA ROSA, CA 95403

EXAMINER
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MEDWAY, SCOTT J

ART UNIT	PAPER NUMBER
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3763

NOTIFICATION DATE	DELIVERY MODE
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08/25/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

rs.vasciplegal@medtronic.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/527,414	<b>Applicant(s)</b> CAMPBELL, TODD	
	<b>Examiner</b> SCOTT MEDWAY	<b>Art Unit</b> 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-3,6-10,12-16 and 18-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3,6-10,12-16 and 18-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03/11/2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 08/04/2009 has been entered.
2. Claims 1-3, 6-10,12-16 and 18-25 are pending.

### ***Claim Objections***

3. Claim 8 is objected to because of the following informalities: the word "anti-restentoic" should be changed to --anti-restenotic-- so as to correct the typographical error. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

**6. Claims 1-3, 6-8, 12-16, 18-20 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kamath et al (WO 2000/32255, hereinafter “Kamath”) in view of Siepmann et al (see *Understanding and Predicting Drug Delivery*, hereinafter “Siepmann”).**

Regarding claims 1-3, 6-8, 12-16, 18-20 and 23, Kamath discloses a medical implant and an associated method for its production, comprising a surface and a coating, having at least two polymer layers incorporating at least two releasable pharmaceutical compounds (pg. 11, lines 17-23), wherein the medical device is, e.g., an expandable vascular stent (pg. 8, lines 12-21) (capable of being self-expanded), and comprises polymer layers made from, e.g. silicones (pg. 15, line 21) or collagen, a known bioresorbable compound (pg. 16, line 1); wherein the pharmaceutical compound is, e.g. a restenotic drug (pg. 25, line 4) and is coupled to the polymer coating by virtue of being embedded therein.

It is noted that Kamath does not disclose the compound incorporated into the polymer layers to have differing physical properties, where the physical property is molecular weight. Siepmann discloses the use of medical devices using layered

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coatings containing pharmaceutical compounds, where the layered coatings with different molecular weights are used to alter the effect of drug delivery (see pg. 308, "Polymer Dissolution" and Fig. 1). Since Kamath teaches that dissolution may ultimately cause drug to be delivered (pg. 24, lines 13-15), it would have been obvious for one of ordinary skill in the art at the time of the invention to try incorporating polymer layers with different molecular weights as suggested by Siepmann, since molecular weight is but one of a finite number of identified and well-known characteristics and altering that characteristic would have been obvious for one of ordinary skill in the art with the expected result of providing an improved drug delivery profile.

Regarding claims 6 and 18, it is noted that Kamath in view of Siepmann does not specifically disclose the molecular weights of the polymer types used for the medical device coating to be in the range of 1 kDa to 100,000 kDa. It would have been obvious to one of ordinary skill in the art at the time of the invention to consider implementing polymer coatings having molecular weights in this range, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

**7. Claims 9, 10, 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kamath et al (WO 2000/32255) in view of Siepmann et al (see *Understanding and Predicting Drug Delivery*), further in view of Shwarz (U.S. Pat. 6,368,658, hereinafter "Shwarz").**

It is noted that Kamath in view of Siepmann does not disclose a macrolide antibiotic such as rapamycin. Shwarz discloses a drug delivery stent comprising rapamycin (col. 4, line 37), which is a known anti-restenotic compound and macrolide antibiotic. Since Kamath discloses the use of a stent for preventing restenosis, it would have been obvious to substitute a macrolide antibiotic such as rapamycin as disclosed by Shwarz for any anti-restenotic compound in Kamath, since rapamycin and the anti-restenotic compounds disclosed by Kamath are functional equivalents and substituting one for the other would be within the level of ordinary skill in the art.

Additionally, it has been held that selecting a known compound such as rapamycin on the basis of its suitability for use as an anti-restenotic compound in stents is within the level of ordinary skill in the art as an obvious design choice. *In re Leshin*, 125 USPQ 416.

### ***Conclusion***

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Applicant is directed to the *Notice of References Cited*.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SCOTT MEDWAY whose telephone number is (571) 270-3656. The examiner can normally be reached on Monday through Friday, 7:30 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on (571) 272-4977. The fax

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phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Scott J. Medway/  
Examiner, AU 3763  
08/17/2009

/Nicholas D Lucchesi/  
Supervisory Patent Examiner, Art Unit 3763